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09/18/2003

Jaime Vargas

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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/665,170  
Filing Date: September 18, 2003  
Appellant(s): VARGAS ET AL.

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Brian A. Schar  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed March 24, 2008 appealing from the Office action mailed March 2, 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

|           |                |         |
|-----------|----------------|---------|
| 6,113,612 | Swanson et al. | 09-2000 |
| 6,461,320 | Yencho et al.  | 10-2002 |

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3, 14, 15, 21, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Yencho et al. (6,461,320). Yencho et al. disclose, at least in figures 24 and 28D and in col. 13, lines 3-14; a method of forming an anastomosis, where the method includes providing a unitary, partially tubular anastomosis device (110), connecting or everting an end of a graft vessel (125) around the anastomosis device, delivering at least a portion of the device into a lumen of a target vessel (127) through an opening in the wall of the target vessel, manipulating, radially expanding, or plastically deforming at least a portion of the anastomosis device with an expander (131) to form a first flange (121) positioned in the lumen of the target vessel and spaced apart from the wall of the target vessel, where manipulating includes completely forming the first flange (within the lumen of the target vessel) and moving it into contact with the wall of the target vessel after the manipulating is complete, where manipulating the anastomosis device includes translating the expander relative to the anastomosis device at joining of the anastomosis device to the expander, and where translating comprises translating the distal end of the expander (at 136 as seen in figure 24) from a position within the anastomosis device to position distal to and outside of the anastomosis device.

Claims 1, 7-13, 16-20, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Swanson et al. (6,113,612). Swanson et al. disclose, at least in figures 2, 3, 7-11, and 15-19 and in col. 4, lines 54-59; col. 7, line 47 to col. 8, line 12; and col. 9,

lines 23-67; a method of forming an anastomosis, where the method includes providing a stainless steel anastomosis device (10), connecting an end of a graft vessel (120) to the anastomosis device, delivering at least a portion of the device into a lumen of a target vessel (300) through an opening in the wall of the target vessel; manipulating an expander (110) relative to the device in order to form a first flange (40) with a plurality of radially arranged elements positioned in the lumen of the target vessel and spaced apart from the wall of the target vessel (see fig. 10, where at least the distal portion of the graft separates the wall of the target vessel from the first flange), where manipulating completely forms the first flange (at inflation of the expander and before contact of element 42 with the target vessel), where the first flange is further moved substantially linearly into contact with the wall of the target vessel (at 42) after completion of the manipulating, where the method includes providing and connecting a separable holder (220) to the device, and moving the holder (220), where the device includes at least one tab (22) at its proximal end for connecting to the holder (see fig. 7), where manipulating the device includes forming a second flange (20) proximal to the first flange and positioned outside and in contact with the target vessel (see fig. 11), where the graft vessel is penetrated with elements 22; where manipulating the device includes moving a portion of one element away from a portion of a different (e.g. opposing) element, and where translating (see at least fig. 7) comprises translating the distal end of the expander (110) from a position within the anastomosis device to a position distal to and outside of the anastomosis device (during the joining of the anastomosis device to the expander).

Additionally, Swanson et al. disclose the method of claim 1 with anastomosis device 410 (see figs. 15-19), where manipulating of the anastomosis device includes completely forming of a first flange (460, 462, or 464) with an expander (a “dual balloon system” or a “single ‘bulbous’ shaped balloon”) prior to moving the first flange into contact with a target vessel.

#### **(10) Response to Argument**

The allegation on page 5, paragraph VII (A), that Yencho does not “describe, or even suggest, completely forming the first flange and only afterward moving that formed flange into contact with the target vessel,” is incorrect. As pointed out in the rejection, Yencho discloses, at least in figure 28D and in col. 13, lines 3-14; that the anastomosis device is “positioned within the target vessel lumen before the distal end flange 121 is deployed, to facilitate deployment thereof.” That is, a flange is formed completely within the lumen of the target vessel before it is moved into contact with the target vessel. Moreover, the flange is deemed to be “completely formed” upon deformation of the anastomosis device or upon any amount of radial expansion of the deformable section of the anastomosis device. In Yencho, a complete flange exists within the lumen of the target vessel (and spaced from the vessel wall) upon even an initial, minute deformation of the deformable section.

The allegation on page 6, paragraph VII(A), that Swanson also does not “expressly or inherently describe the claimed ‘manipulating [that] completely forms said first flange; and moving said first flange into contact with the wall of the target vessel after said manipulating is complete,’” is incorrect. As pointed out in the rejection, the

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first flange is deemed to be element 40 (which includes element 42), and it is formed by deformation of the anastomosis device (10). As in Yencho, a complete flange (elements 40 and 42 combined) exists within the lumen target vessel (and spaced from the target vessel wall) upon the initial deformation the distal portion of the anastomosis device. In other words, there is a point during deformation of the anastomosis device, where the combination of elements 40 and 42 extends radially (i.e., completely forms a flange) and does not contact or penetrate the target vessel wall.

In short, Yencho and Swanson each describe, expressly and inherently, each and every element claimed in base claim 1, where, a first flange is "completely formed," albeit the flange may not be completely deployed, before it is moved into contact with the wall of the target vessel.

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**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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TQAS TC 3700